

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

12

EUROPEAN PATENT APPLICATION

21 Application number: 84420185.5

51 Int. Cl.: **A 61 F 2/30, A 61 F 2/32**

22 Date of filing: 30.10.84

30 Priority: 04.11.83 US 548717

71 Applicant: Howmet Turbine Components Corporation,
475 Steamboat Road, Greenwich, CT 06830 (US)

43 Date of publication of application: 19.06.85
Bulletin 85/25

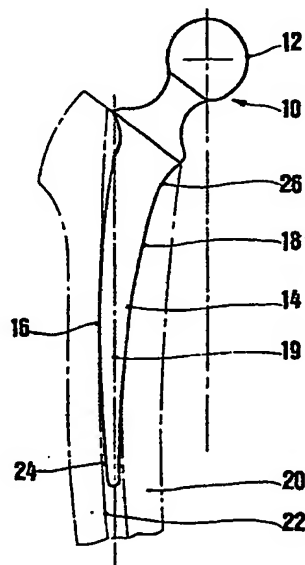
72 Inventor: Carozza, Eugene J., 38 Jay Street, Succasunna
New Jersey 07876 (US)
Inventor: Burd, Lamar, 13 Smith Street, Andover New
Jersey 07821 (US)
Inventor: Miller, Evan R., Apt. 22D Village Green, Budd
Lake New Jersey 07828 (US)

84 Designated Contracting States: DE FR GB IT

74 Representative: Séraphin, Léon et al, PECHINEY 28, rue
de Bonnel, F-69433 Lyon Cedex 3 (FR)

54 Anisotropic surgical prosthesis.

57 A cast metal prosthetic implant (10) disposed to replace a portion of the natural skeleton. The implant is formed in a manner to render the casting (10) anisotropic. The minimum elastic modulus of the casting (10) is aligned with the direction of maximum stress in the implant to reduce the stress induced by the implant on the skeleton. A method of casting a metal prosthetic device by controlling solidification of the casting such that the casting is anisotropic and a specific crystallographic direction in the casting is aligned with the direction of maximum stress applied to the casting during use.



EP 0 145 617 A2

BACKGROUND OF THE INVENTION

The invention relates to metal prosthetic devices disposed to replace portions of the skeletal system. More particularly, the invention relates to an improved femoral insert used in hip replacement surgery.

The replacement of a defective hip joint with an implanted member is one of the significant recent advances of orthopedic surgery. Such implants are subjected to unique constraints. The materials used must be compatible with surrounding tissue, the materials must be strong and capable of being formed into relatively complex shapes, and, in addition, such members are subjected to significant mechanical loads that must be transmitted to the natural portions of the skeleton that interface with the prosthetic device. The replacement for the head of the femur normally has a stem that is implanted into the intermedullary cavity of the femur and is affixed by cement or by the growth of bone onto or into the surface of the stem. In order to minimize the removal of material from the intermedullary cavity of the femur, the stem must be relatively slender. The loads on the stem, however, require that the material be strong.

A problem arises when a strong relatively slender metal member transmits applied loads to the surrounding bone. Some stress on the bone is necessary to prevent resorption, however; the load should be distributed as opposed to concentrated or local loading. Metal stems are normally formed of polycrystalline metal having a high elastic modulus and a flexural load applied to the stem deflects the stem significantly less than the surrounding bone. This can result in high local stresses and cause a detachment of the stem from the bone or the stem may actually fracture the surrounding bone.

0145617

One object of the present invention is to construct a prosthetic device having an elastic modulus that more closely matches that of the surrounding bone.

5 An additional object of the invention is to provide a metal device that has an anisotropic elastic modulus with the minimum elastic modulus being aligned with the direction of maximum stress in the device such that strain on the bone surrounding the device is minimized.

10 A further object of the invention is to provide means for distributing the load applied by the prosthetic device to the surrounding bone to reduce high local stresses.

Other objects and advantages of the invention will be apparent from the description of the preferred embodiment or will be apparent from the practice of the invention.

15 SUMMARY OF THE INVENTION

The invention broadly disclosed herein is a metal prosthetic device comprised of a cast metal member that is disposed to replace a portion of the natural skeletal system. In a preferred embodiment, the device is a replacement of the head of the femur.

20 The metal member of the invention is cast in such a manner that its elastic modulus is anisotropic. The minimum elastic modulus of the metal member is aligned in the prosthetic device such that flexure of the device imparts minimum stress to the natural skeletal system interfaced with the device. Preferably, the
25 metal is of a cubic crystal structure with either the [001], [010] or the [100], crystal direction being aligned with the direction of maximum stress on the device.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a cross-sectional view of a femur having one embodiment of the invention implanted therein.

Fig. 2 is a cross-sectional view of one type of mold used to produce a single crystal hip prosthesis.

Fig. 3 is a cross-sectional view of another type of mold used to produce a single crystal hip prosthesis.

Fig. 4 is a cross-sectional view of still another type of mold used to produce a directionally solidified polycrystalline hip prosthesis.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The invention is a prosthetic device that is disposed to replace a portion of the natural skeleton. The most commonly replaced portion of the human skeleton is the head of the femur and the acetabular joint in which it fits. It is the replacement for the head of the femur that is the principal application for the present invention and the disclosed embodiment is such a device. The invention, however, is broader than just a prosthetic replacement for the head of the femur and may be used in connection with other prosthetic devices that are implanted in bone and subjected to significant stress.

In accordance with the invention, the device is comprised of a cast metal member. The particular metal used must be compatible with its unique environment, and those skilled in the art are capable of selecting a metal or metal alloy suitable for implanting in such an application. In addition to the normal requirements of biocompatibility and strength, the present invention requires that the metal used be capable of being cast in such a manner as to render its elastic modulus anisotropic.

0145617

Preferably, this is accomplished by casting the metal to form a single crystal, but a directionally solidified casting having a predetermined grain shape and orientation may provide sufficient anisotropy to provide the desired effect on the elastic modulus of the casting.

Preferably, the metal comprising the casting has a cubic crystallographic structure. One type of metal alloy which is known to be operable with the invention is the cobalt-chromium alloy, ASTM F 75, conventionally used in such prosthetic devices.

0 For such a material it is possible to reduce the elastic modulus of a single crystal casting in a specific crystallographic direction by approximately 40%. For this particular alloy (which is typical of cubic metals) the direction of minimum elastic modulus is parallel to the edges of the cubic unit cell, i.e. the [001],
5 [010] or [100] directions. The advantage of this reduction of the elastic modulus will be apparent from the description of the preferred embodiment.

Materials other than cubic metals also may be used with the present invention. Titanium and its alloys are known to be
0 useful as a material for prosthetic devices; however, forming titanium as a single crystal that is stable at room temperature is difficult.

As noted above, it is preferred that the device be a single crystal. Not only can the anisotropy be controlled in such a
5 structure but the lack of grain boundaries may allow the use of materials that would otherwise have undesirable properties due to grain boundary conditions. Use of single crystals also may allow the elimination of alloy constituents normally necessary to control grain boundary effects.

Fig. 1 depicts a surgical prosthesis disposed to replace the head of the femur and engage the acetabular joint in the pelvis.

The device of Fig. 1, shown generally as 10, has an acetabular portion 12 and a femoral portion or stem 14. The device 10 is implanted in the head of the femur 20 in a conventional manner. The load transmitted to the femur 20 is applied through the acetabular portion 12 and the stem 14. As is apparent from Fig.

1, the applied load is not coincident with the center of the femur 20 or the stem 14 so that a bending load is imposed on the stem.

As noted previously, the cross-sectional size of the stem is preferably small to reduce the amount of material that must be removed from the intermedullary cavity 22. In order for the stem 14 to withstand the relatively large imposed loads it must have a high elastic modulus. Yet when loads are applied through such a device, its elastic modulus is so much higher than that of the surrounding bone that shear stresses are set up at the prosthesis/bone interface. This can break the bond between the bone and the prosthesis. More drastic loading, either by higher loads or smaller stems, may actually cause rotation of the stem within the femur in response to the applied torque of the offset load and break the femur at the outer distal region 24, the inner proximal region 26 or both.

In the embodiment depicted, the load applied to the acetabular portion 12 creates a bending stress in the stem 14 in the direction of the arrow in Fig. 1. This creates maximum stress on the outer surface 16 and the inner surface 18 which are roughly parallel to the centerline 19 of the stem 14. Therefore, it is desired to reduce the elastic modulus in the direction of

maximum applied stress, i.e. parallel to the centerline of the stem. In a cubic metal this is accomplished by aligning any of the edges of the unit cell of the cubic crystal with the centerline of the member under bending stress.

5 The alignment of certain crystallographic directions with the specific portion of the prosthetic device is accomplished by controlling the direction and rate of heat extraction during casting of the device. Metallic materials solidify during casting when heat is removed from the melt by forming as a solid on
10 existing solid material. If casting conditions are controlled, the melt can be made to solidify only on small solid particles of the melt material itself (rather than the mold or other solid particles in the melt), and, by limiting the number of such solid particles (nuclei) and controlling the direction of heat extrac-
15 tion from the melt, the melt can be solidified as a single crystal or a relatively small number of crystals aligned with the direction of heat extraction.

Cubic metals solidify at a higher rate along certain crystallographic directions, and this feature can be used to align
20 such directions with the particular device being cast. In addition, metals can be made to solidify on an existing solid of the same metal in the same orientation as the solid. Therefore, by orienting the solid on which solidification is initiated, the crystallographic orientation of the casting may be oriented.

25 Fig. 2 depicts a mold 30 for casting a hip prosthesis using a small solid termed a "seed crystal" 31, to orient the crystallographic direction of the final casting. This embodiment is used to form a single crystal where all crystallographic directions are predetermined by the orientation of the seed crystal.

The casting is shaped in the mold cavity 32 formed by a ceramic shell 34. The manner of producing such a mold is readily apparent to those skilled in the art of investment casting of metals. The mold 30 further includes a seed cavity 36 and a heat sink or "chill" 38. It is the function of the chill 38 to extract heat from the casting in contact with it thereby imparting a direction to the heat flow from the melt forming the casting. By manipulation of the temperature surrounding the ceramic shell 34, the temperature of the melt and the rate of heat extraction from the melt, the casting can be formed by solidification from the bottom up at a rate where the metal will only nucleate and grow as a single crystal.

To control the orientation of the single crystal being formed, the seed crystal 31 is placed within the seed cavity 36. The seed crystal has a known crystallographic orientation, and the orientation of the seed crystal within the seed cavity determines the orientation of the final casting. If, for example, the [001] direction of a cubic crystal is to be aligned with the centerline of the casting, that direction is oriented in the seed crystal to be parallel to the centerline. Upon initiation of the casting process the upper portion of the seed crystal is melted and the mold cavity filled. The extraction of heat from the melt through the seed crystal induces solidification at the seed/melt interface and the melt is solidified progressively from the seed crystal upward. If casting conditions are correct, the melt will solidify only in the orientation of the seed crystal as a single crystal. Those skilled in the art of casting metal single crystals can readily determine the casting conditions needed to produce an article in such a form.

This method has an advantage over other methods of directionally solidifying metals because the orientation of the crystallographic directions of the casting can be controlled in all directions. This will be more clearly apparent when the alternative method of casting such a device, depicted in Fig. 3, is disclosed.

Fig. 3 depicts a mold 40 having a mold cavity 42 formed by a ceramic shell 44. The mold further includes a crystal selector 46, a growth cavity 47 in flow communication with the mold cavity 42 and a heat extracting member or chill 48.

When molten metal is poured into the mold cavity 42, it fills the selector 46 and the growth cavity 47 and solidification is initiated at the surface of the chill 48. While the orientation of the solidified metal upon initial solidification is random, the rate of solidification in crystalline materials is not the same in all crystallographic directions. Thus, as the melt solidifies as a solid/liquid interface moving upward in the growth cavity 47, certain solid crystals having certain crystal-line orientations will be favored due to their more rapid rate of growth. The selector 46 will, because of its curvature, "select" from the advancing solid the crystal that is most rapidly advancing. At the exit of the selector 46, at the lower extremity of the mold cavity, the crystal being formed will have the crystal-line direction that most rapidly solidifies aligned with the centerline of the mold.

In a cubic metal the crystallographic directions parallel to the edges of the cube are aligned with the direction of heat extraction. Therefore, these three directions are most favored to be aligned with the centerline of the mold cavity at its lower extremity.

Unlike the seed crystal method, however, only one direction of the crystal can be controlled. In other words, if the [001] direction is parallel to the centerline of the mold, the [010] and [100] directions are mutually perpendicular but may be rotated at any orientation 360° around the [001] direction. By contrast, the seed crystal method controls the orientation of all crystallographic directions by orienting the seed crystal.

As noted above, the invention has been disclosed in terms of embodiments that are single crystals. One skilled in the art may use such teachings to produce an article having more than one crystal that nevertheless provides the benefits of the invention. For example, a polycrystalline member having the crystals or grains parallel to the direction of maximum stress with the orientation of the crystals aligned to reduce the elastic modulus in that direction would still be within the scope of the present invention.

Fig. 4 depicts a mold for making a directionally solidified casting. The mold 50 forms a mold cavity 52 utilizing a ceramic shell 54. The mold further includes a chill cavity 56 in contact with the chill 58. During the casting operation heat is directionally extracted from the melt such that solidification initiates at the chill surface within the chill cavity 56 with the liquid/solid interface moving upward. Appropriate control of heat flow, mold and melt temperatures and possible nucleation sites allows the formation of a polycrystalline casting having elongated grains aligned with the approximate centerline of the mold cavity 52.

Other embodiments of the invention will be apparent to those skilled in the art. The scope of the invention is not limited to

the embodiments disclosed but is defined by the appended claims and their equivalents.

WHAT IS CLAIMED IS

1. A metal prosthetic device comprising : a cast metal member (10) disposed to replace a portion of the natural skeletal system, the elastic modulus of said metal member (10) being anisotropic, the
5 minimum elastic modulus of said metal member (10) being aligned with the direction of maximum stress on said device, whereby the flexure of said device imparts minimum stress to the natural skeletal system interfaced with said device.
- 10 2. The device of Claim 1 wherein said device is a single crystal.
3. The device of Claim 2 wherein said metal comprises a cobalt-chromium alloy.
- 15 4. The device of Claim 2 wherein said crystal is cubic.
5. The device of Claim 4 wherein the single crystal has a crystal edge direction selected from the group consisting of $[001]$,
20 $[010]$ and $[100]$ generally aligned with the direction of maximum stress on said device.
6. The device of Claim 1 wherein said device is a hip prosthesis disposed to be implanted in the femur.
- 25 7. A surgical prosthesis disposed to be implanted in the femur (20) to replace the head of the femur, said prosthesis comprising : a femoral portion (14) and an acetabular portion (12), said femoral portion (14) being comprised of a single crystal of a cubic metal
30 having a crystal direction selected from the group consisting of $[001]$ $[010]$ and $[100]$ aligned to be parallel with the centerline of said femoral portion (14).
8. The surgical prosthesis of Claim 7 wherein said metal is a
35 cobalt-chromium alloy.

9. The surgical prosthesis of Claim 8 wherein said metal is an alloy designated as ASTM F 75.

10. A method for casting a metal prosthetic device out of molten metal being capable of being formed into an anisotropic casting, said method utilizing means (32; 42; 52) for shaping said casting, means (38; 48; 58) for extracting heat from said molten metal within said shaping means, and means (31; 46, 57; 56) between said shaping means (32; 42; 52) and said heat extracting means (38; 48; 58) for orienting at least one crystallographic direction of said casting, said method comprising the steps of:

- a) placing molten metal within said shaping means (32; 42; 52)
- b) controlling heat extraction from said molten metal such that heat flows primarily to said heat extracting member (38; 48; 58) so as to form an anisotropic casting;
- c) aligning a crystallographic direction in said casting with the direction in said device receiving maximum applied stress to reduce the elastic modulus of said casting in said direction.

11. The method of Claim 10 including the step of placing a seed crystal (31) between said molten metal and said heat extracting member (38).

12. The method of Claim 10 including the step of selecting a single crystal forming in said molten metal and growing said single crystal in alignment with said crystallographic direction.

13. The method of Claim 10 wherein said casting is a single crystal.

14. The method of Claim 14 wherein said single crystal is a cubic metal.

15. The method of Claim 14 wherein said metal is a cobalt-chromium alloy.

16. The method of Claim 15 wherein said metal is ASTM F 75.

1-2

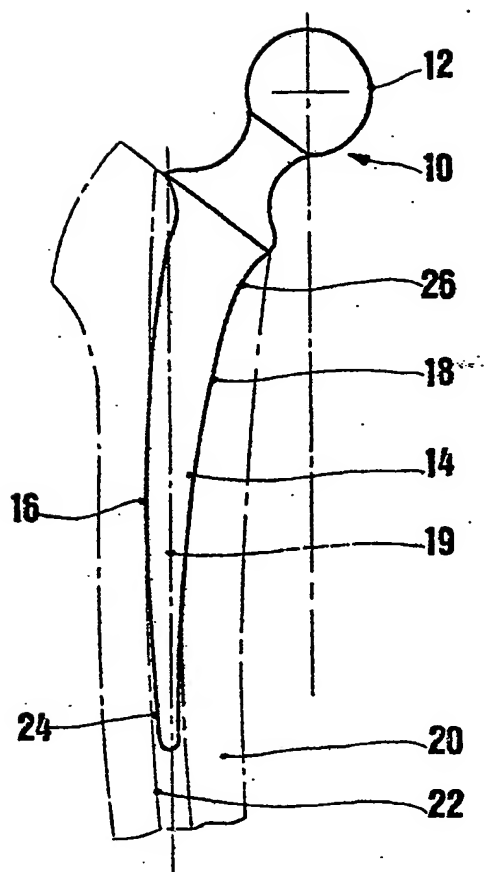


FIG. 1

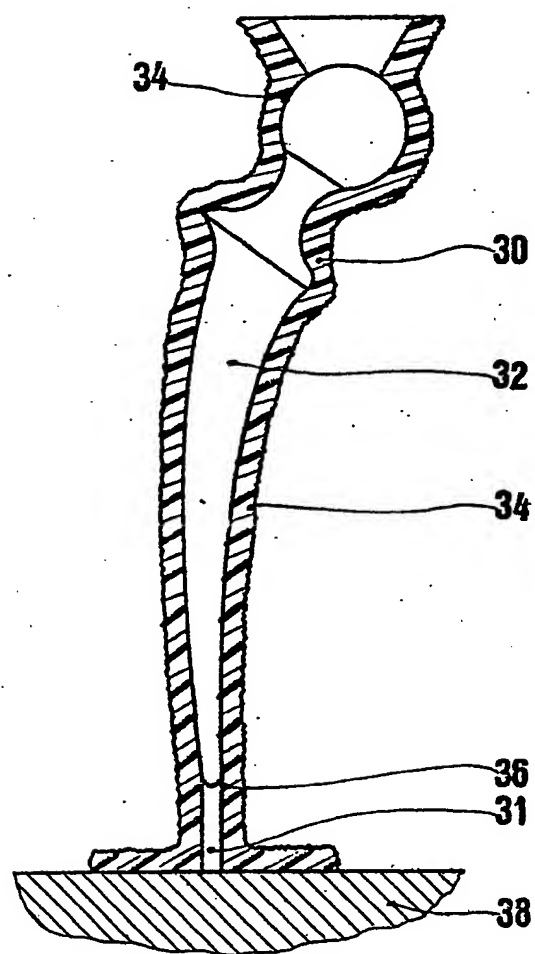


FIG. 2

2-2

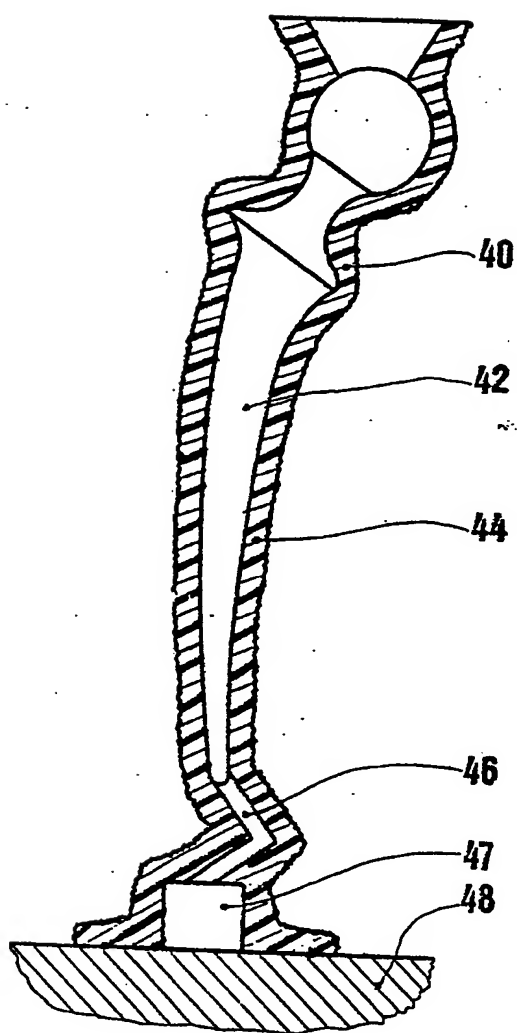


FIG. 3

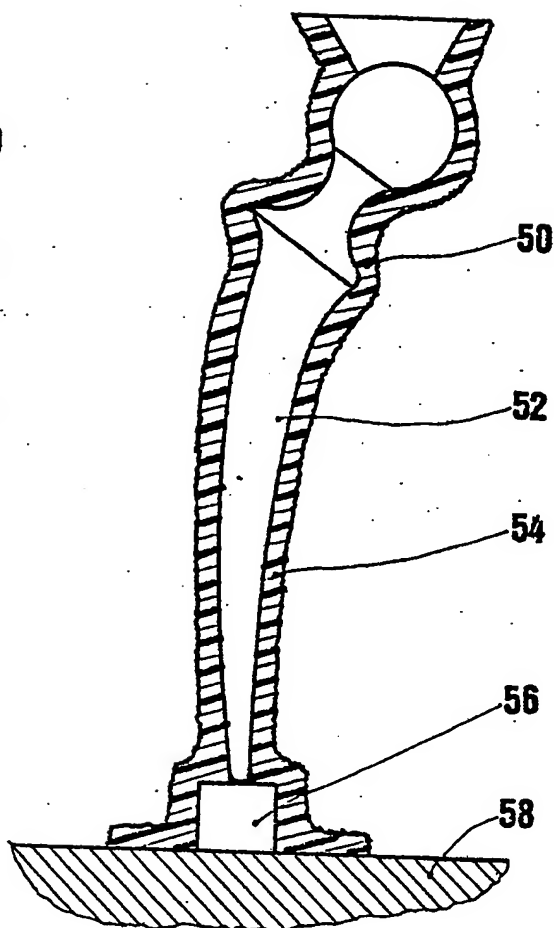


FIG. 4